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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,113	03/22/2000	Joseph R. Byrum	38-21(15761)B (16517.001)	4899
27161	7590	11/30/2006	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/531,113

Applicant(s)

BYRUM ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 8 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 8 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **FINAL ACTION**

1. Applicant's amendment filed 9/7/2006 is acknowledged and has been entered. Claims 1, 8 and 13 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

#### **This action is made FINAL**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Previous Rejections***

3. The claim rejection under 35 USC 101 and 35 USC 112 first paragraph directed to claims 1, 8 and 13 as lacking utility is maintained and discussed below.

I. **Issue: The claims 1, 8 and 13 are rejected under 35 USC 101 because the claimed invention lacks patentable utility due to its not being supported by either a specific and/or substantial utility or a well established utility.**

#### ***Applicant's Traversal***

4. Applicant traverses the rejection on the following grounds: Applicant summarizes the Examiner's rejection and states that a BLASTN analysis is a well known and conventional technique for one of ordinary skill in the art. Applicant states that the results of a BLASTN analysis of the claimed SEQ ID NO: 5981 is shown below. As these results show, the claimed nucleotide sequence shows 94 percent identity of a sequence obtained from water-stressed Glycine max. Applicant states that the sequence was obtained by Valliyodan, B., Huang, S., Joshi T., Hernandez, A., Spollen W.G., Bohnert, H.J., Duke, M.V., Liu X., Scheffler, B.E., Sharp,

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R.E., Xu, D., Springer, G.K., Stacey, G and Nguyen, H.T. in an unpublished 2005 study entitled "EST analysis of Soybean Root Tip under Drought Stress: MSMC Grant 002245 - Development and Deployment of Biotechnology Tools for Soybean Improvement".

Applicant states that in other words, the claimed nucleotide sequence has utilities specific to it and not generally applicable to any nucleic acid. Applicant states that for example, the claimed nucleic acid sequence can be used to isolated genes, map genes, and determine gene function associated with water stress. Applicant states that theses utilities are credible, substantial and well established; they are neither vague nor impractical. Applicant states that the Applicant need only establish a single utility to satisfy 35 USC 101 and have done so in the present case. Applicant reminds the Examiner that the utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. Applicant further reminds the Examiner that 'a rigorous correlation' need not be shown in order to establish a practical utility; 'reasonable correlation' is sufficient. Applicant asserts that an applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence or any combination thereof. Applicant states that the BLASTN analysis provides such a reasonable correlation through sequence identity: a 94 percent identity to a sequence obtained from water-stressed *Glycine max* is a reasonable correlation. In conclusion, Applicant states that Applicant needs only establish a single utility to satisfy 35 USC 101 and have done so with sufficient specificity and reasonable correlation in the present applicant.

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***Examiner's Response***

5. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: The examiner acknowledges Applicant's arguments but maintain that the instant invention lacks either a "single" specific and/or substantial utility or a "single" well established utility. MPEP 2107 states that:

"[A] "specific utility" is specific to the subject matter claimed and can "provide a well-defined and particular benefit to the public." In re Fisher, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005). This contrasts with a general utility that would be applicable to the broad class of the invention. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. >See, e.g., In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967); In re Joly, 376 F.2d 906, 153 USPQ 45 (CCPA 1967).< Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. >See In re Fisher, 421 F.3d at 1374, 76 USPQ2d at 1232 ("Any EST [expressed sequence tag] transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses.... Nothing about [applicant's] seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the [ ] application or indeed from any EST derived from any organism. Accordingly, we conclude that [applicant] has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.")< A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed".

In this case that fact that Applicant has identified an EST sequence from soybean that shares 94% identity to water-stressed Glycine max does not identify a specific use for the claimed sequence. There is nothing about the alleged use of SEQ ID NO: 5981 as claimed that set it apart from the other 48,629 other EST sequences disclosed in the current application or any other EST derived from any other organism or plant. Therefore, Applicant has only disclosed a general use for its claimed EST, not a specific utility that satisfy the requirement of 35 USC 101. MPEP 2107 further states in regards to a substantial utility that:

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“[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” Fisher, 421 F.3d at 1371, 76 USPQ2d at 1230. The claims at issue in Fisher were directed to expressed sequence tags (ESTs), which are short nucleotide sequences that can be used to discover what genes and downstream proteins are expressed in a cell. The court held that “the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant’s] research effort, but only tools to be used along the way in the search for a practical utility.... [Applicant] does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.” Id. at 1376, 76 USPQ2d at 1233-34). Thus a “substantial utility” defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities.”

In this case, the instant invention is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. The research contemplated by Applicant to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying properties of a protein itself, e.g., percent identity, or the mechanisms in which the protein is involved does not define a “real world” context or use. Similarly, the claimed use of the nucleic acid in the instant invention is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic acid molecules. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggest any properties or activities for the nucleic acid or the encoded protein such that another non-asserted utility would be well established for the EST sequence of SEQ ID NO: 5981.

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Applicant arguments are not sufficient to overcome the prior art rejection under 35 USC 101. Accordingly, the rejection is maintained.

**II. Issue: Claims 1, 8 and 13 are rejected under 35 USC 112, first paragraph.**

***Applicant's traversal and Examiner's response***

6. Applicant states that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 USC 101.

In response to Applicant's arguments, the Examiner maintains that the rejection has not been overcome as set forth in the Examiner's response set forth above at #5. The examiner maintains that the claims do not satisfy the requirements of 35 USC 101 or 25 USC 112, first paragraph. Applicant's arguments are not sufficient to overcome this rejection. Accordingly, the rejection under 35 USC 112 first paragraph is maintained.

***Conclusion***

7. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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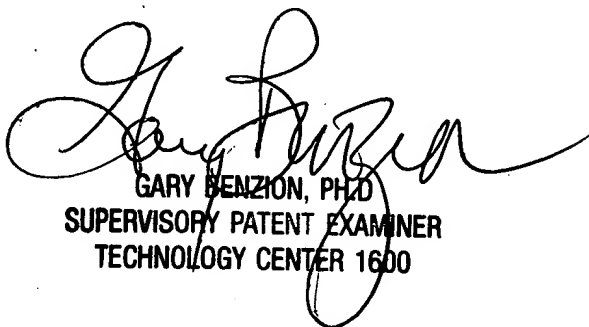
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw



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